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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: EnaCem

· Article number: CPC, CPC-3

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture Dental Cement

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Micerium spa., Via G. Marconi, 83 - 16036 Avegno (GE), Italy, Tel.: +39-0185-7887870, Fax: +39-0185-7887970

- · Further information obtainable from: Dr. Eugenio Miceli
- · 1.4 Emergency telephone number:

Poison Control Center San Martino Hospital (Genoa, Italy) Tel.: +39-010-352808 (available 24 h)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS07

- · Signal word Warning
- Hazard-determining components of labelling:

tetramethylene dimethacrylate

dibenzoyl peroxide

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Labelling of packages where the contents do not exceed 125 ml
- · Hazard pictograms



GHS07

- · Signal word Warning
- Hazard-determining components of labelling:

tetramethylene dimethacrylate

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dibenzoyl peroxide

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · **Description:** Adhesive material for dental use.

	· Dangerous components:			
Г		· · · · · · · · · · · · · · · · · · ·	2.5-10%	
	EINECS: 218-218-1	💠 Skin Sens. 1B, H317		
	CAS: 94-36-0	dibenzoyl peroxide	<2.5%	
	EINECS: 202-327-6	📀 📀 Org. Perox. B, H241; 🗘 Eye Irrit. 2, H319; Skin Sens. 1, H317		
	CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	<2.5%	
	EINECS: 278-355-8	🕸 Repr. 2, H361f; 🍫 Aquatic Chronic 2, H411; 🔱 Skin Sens. 1B, H317		

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information Immediately remove any clothing soiled by the product.
- · After inhalation

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

- · After eye contact Rinse opened eye for several minutes under running water.
- · After swallowing

Rinse out mouth and then drink plenty of water.

Call a doctor immediately.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

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· 5.3 Advice for firefighters

· Protective equipment: Adapt to environment.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid eye and skin contact with the substance.

- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Keep away from heat and direct sunlight.
- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- Requirements to be met by storerooms and receptacles:

Close container immediately after use and protect product from light incidence.

Store in refrigerator.

- Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: Protect from heat and direct sunlight.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures Avoid contact with the eyes and skin.
- · Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands: Protective gloves.
- · Material of gloves

Butyl rubber, BR

Nitrile rubber, NBR

· Penetration time of glove material

0.3 mm

Penetration time 60 min.

0.11 mm

Penetration time 10 min.

· Eye protection: Safety glasses

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· Body protection: Protective work clothing.

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SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Viscous
Colour: Yellowish

• Odour: Weak, characteristic• Odour threshold: Not determined.

• pH-value: Not determined.

· Change in condition

Melting point/freezing point: < - 20 ° C Initial boiling point and boiling range: 251 °C

· Flash point: 101 °C

· Flammability (solid, gaseous) Not applicable.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

Not determined.

· Explosion limits:

Lower:

Upper:Not determined.Vapour pressure:1,3 mbar (110 ° C)

Density: Not determined
 Relative density Not determined
 Vapour density Not determined
 Evaporation rate Not determined

· Solubility in / Miscibility with

Water: Not miscible or difficult to mix

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

dynamic: Not determined. kinematic: Not determined.

· Solvent content:

Solids content: 0.0 %

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions Exothermic polymerization
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials:

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:

tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat) dibenzoyl peroxide: 78 % in water oral > 5000 mg/kg rat

inhalation > 24,3 mg/1/4h rat

N,N-Bis(2-hydroxyethyl)-p-toluidine LD-50 oral 300 mg/kg rat

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation

May cause an allergic skin reaction.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

08 04 10 waste adhesives and sealants other than those mentioned in 08 04 09

- · Uncleaned packaging:
- · Recommendation:

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning. Packagings that may not be cleansed are to be disposed of in the same manner as the product.

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· Recommended cleansing agents: Ethyl acetate

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· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · National regulations
- · Technical instructions (air):

Class	Share in %
III	2.5-10

- · Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects.

- · Department issuing SDS: Micerium S.p.a.
- · Contact: Dr. Eugenio Miceli

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· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides - Type B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B Repr. 2: Reproductive toxicity – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

* Data compared to the previous version altered.

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